



Attorney's Docket No: C1039.70044US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Hartmann et al.  
Serial No. : 09/672,126  
Conf. No.: 6887  
US Filing Date : 27 September 2000  
For : METHODS RELATED TO IMMUNOSTIMULATORY NUCLEIC  
ACID-INDUCED INTERFERON  
Examiner : Q. Nguyen  
Art Unit : 1632

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 11th day of December, 2003.

*Adele E. Stone*  
Adele E. Stone

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

Copy of previously-submitted Information Disclosure Statement, Form PTO-1449, References Cited, Return Receipt Postcard, and Return Receipt Postcard stamped received by the USPTO on Jan. 16, 2001  
 Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No check is enclosed. If a fee is determined to be required, the balance may be charged to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,

By: 

Alan W. Steele, Reg. No. 45,128  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, MA 02210  
Telephone (617) 720-3500

Docket No. C1039.70044US00  
Dated: December 11, 2003  
xNDDx



DEC 18 2003

Serial No. 09/1672,126 File No. 2103917044 By: Ans

Title: METHODS RELATED TO IMMUNOSTIMULATORY NUCLEAR ACID...

Application of Hartmann et al. WGS Date: ADD

The U.S. PTO Mail Room acknowledges receipt of the following on the date stamped hereon:

<input type="checkbox"/> Mailing by Express Mail (37 CFR 1.10) Express Mail Label No. _____	<input type="checkbox"/> Provisional Application Cover Sheet Multiple Dependent Claim Fee Sheet Inf. Discl. Statement, PTO Form 1449
<input type="checkbox"/> Patent Application [ <input type="checkbox"/> Non-provisional <input type="checkbox"/> Provisional Incl. _____ pages, ( _____ pgs) Specification, ( _____ pgs) Abstract, ( _____ pgs) Claims ( _____ # claims)	<input checked="" type="checkbox"/> References Cited Priority Document(s) # _____
<input type="checkbox"/> Design Patent Application Declaration(s) Drawings _____ Sheet(s) (FIGS. _____) [ <input type="checkbox"/> Formal <input type="checkbox"/> Informal	<input type="checkbox"/> Copy of Notice to File Missing Parts
<input type="checkbox"/> Utility Patent Application Transmittal Fee calculation sheet (x2)	<input type="checkbox"/> Amendment/Response
<input type="checkbox"/> CPA Transmittal	<input type="checkbox"/> Petition for Ext. of Time (x2)
<input type="checkbox"/> Verified Statement claiming small entity status	<input type="checkbox"/> Issue Fee Transmittal
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Other \_\_\_\_\_

DATE MAILED January 10, 2001

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Serial No. 09/1672,126 File No. 2103917044 By: Ans

Title: METHODS RELATED TO IMMUNOSTIMULATORY NUCLEAR ACID...

Application of Hartmann et al. WGS Date: ADD

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<input type="checkbox"/> Patent Application [ <input type="checkbox"/> Non-provisional <input type="checkbox"/> Provisional Incl. _____ pages, ( _____ pgs) Specification, ( _____ pgs) Abstract, ( _____ pgs) Claims ( _____ # claims)	<input checked="" type="checkbox"/> References Cited Priority Document(s) # _____
<input type="checkbox"/> Design Patent Application Declaration(s) Drawings _____ Sheet(s) (FIGS. _____) [ <input type="checkbox"/> Formal <input type="checkbox"/> Informal	<input type="checkbox"/> Copy of Notice to File Missing Parts
<input type="checkbox"/> Utility Patent Application Transmittal Fee calculation sheet (x2)	<input type="checkbox"/> Amendment/Response
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DATE MAILED January 10, 2001



ATTORNEY'S DOCKET NO: C1039/7044 (AWS)

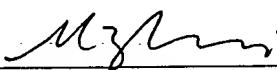
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Hartmann et al.  
Serial No: 09/672,126  
Filed: 27 September 2000  
For: METHODS RELATED TO IMMUNOSTIMULATORY NUCLEIC  
ACID-INDUCED INTERFERON  
Examiner: unassigned  
Art Unit: 1646

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The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 10th day of January, 2001.

  
Monica E. Zombori

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Commissioner for Patents  
Washington, D.C. 20231

Sir:

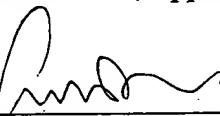
Transmitted herewith are the following documents:

- Information Disclosure Statement
- Form PTO-1449 and References Cited
- Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

No check is enclosed. If a fee is determined to be required, the balance may be charged to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
*Hartmann et al.*, Applicant(s)

By: 

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Docket No. C1039/7044 (AWS)  
Dated: January 10, 2001



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Alan W. Steele, Reg. No. : 45,128

Commissioner for Patents  
Washington, D.C. 20231

STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

PART III: Remarks

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

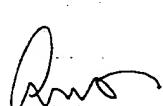
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Hartmann et al.*, Applicant(s)

By: 

Alan W. Steele, Reg. No. 45,128  
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Boston, MA 02210  
Telephone (617) 720-3500

Docket No. C1039/7044 (AWS)  
Dated: January 10, 2001

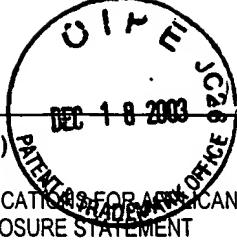
FORM PTO-1449(Modified) LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
		APPLICANT Hartmann et al.	
		FILING DATE September 27, 2000	GROUP 1646

### U.S. PATENT DOCUMENTS

Exam Init	Ref Des	Document No.	Date	Name	Class	Sub Class	FILING DATE If Appropriate
	A1	3,906,092	09/16/75	Hilleman et al.	424	89	
	A2	4,469,863	09/04/84	Ts'o et al.	536	24.5	
	A3	5,023,243	06/11/91	Tullis	514	44	
	A4	5,248,670	09/28/93	Draper et al.	514	454	
	A5	5,359,052	10/25/94	Stee et al.	536	26.7	
	A6	5,512,668	04/30/96	Stec et al.	536	25.33	
	A7	5,585,479	12/17/96	Hoke et al.	536	24.5	
	A8	5,635,363	06/03/97	Altman et al.	435	7.24	
	A9	5,663,153	09/02/97	Hutcherson et al.	514	44	
	A10	5,723,335	03/03/98	Hutcherson et al.	435	375	
	A11	5,786,189	07/28/98	Locht et al.	424	200.1	
	A12	5,849,719	12/15/98	Carson et al.	514	44	
	A13	5,856,465	01/05/99	Stec et al.	536	25.3	
	A14	5,883,237	03/16/99	Stec et al.	536	23.1	

### FOREIGN PATENT DOCUMENTS

		Country & Doc. No. (11)	Pub. Date (43)		Class	Sub Class	Translation Yes No
	B1	EP 0302758 B1	02/08/89	EPO	C12N	15/37	
	B2	EP 0174143 B1	11/08/89	EPO	C07K	15/26	
	B3	WO 91/12811	09/05/91	WIPO	A61K	31/70	
	B4	EP 0468520 A2	01/29/92	EPO	A61K	31/70	
	B5	WO 92/03456	04/05/92	WIPO	C07H	15/12	
	B6	EP 0092574 B1	04/29/92	EPO	C07H	21/02	
	B7	WO 92/18522	10/29/92	WIPO	C07H	21/00	
	B8	WO 92/21353	12/10/92	WIPO	A61K	31/70	
	B9	WO 94/19945	09/15/94	WIPO	A01N	43/04	
	B10	WO 95/05853	03/02/95	WIPO	A61K	48/00	
	B11	WO 95/26204	10/05/95	WIPO	A61K	48/00	
	B12	WO 96/02555	02/01/96	WIPO	C07H	21/00	
	B13	WO 96/35782	11/14/96	WIPO	C12N	15/11	
	B14	WO 97/28259	08/07/97	WIPO	C12N	15/00	
	B15	WO 98/14210	04/09/98	WIPO	A61K	39/35	
	B16	WO 98/18810	05/07/98	WIPO	C07H	21/00	
	B17	WO 98/37919	09/03/98	WIPO	A61K	49/00	
	B18	WO 98/40100	09/17/98	WIPO	A61K	39/39	
	B19	WO 98/52581	11/26/98	WIPO	A61K	35/00	



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FORM PTO-1449(Modified)		ATTY. DOCKET NO. C1039/7044	SERIAL NO. 09/672,126
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT		APPLICANT Hartmann et al.	
		FILING DATE September 27, 2000	GROUP 1646

**OTHER ART**  
(Including Author, Title, Date, Pertinent Pages, Publication, Etc.)

DEC 1 8 2003 U.S. PATENT & TRADEMARK OFFICE CJC	C1	Altman JD et al. Phenotypic analysis of antigen-specific T lymphocytes. <i>Science</i> 1996 Oct 4;274(5284):94-8.
	C2	Ballas ZK et al. Induction of NK activity in murine and human cells by CpG motifs in oligodeoxynucleotides and bacterial DNA. <i>J Immunol</i> 1996 Sep 1;157(5):1840-5.
	C3	Banchereau J and Steinman RM. Dendritic cells and the control of immunity. <i>Nature</i> 1998 Mar 19;392(6673):245-52.
	C4	Beaucage SL and Caruthers MH. Deoxynucleoside phosphoramidites - a new class of key intermediates for deoxypolynucleotide synthesis. <i>Tetrahedron Lett</i> 1981;22(20):1859-62.
	C5	Cascinu S et al. A phase I trial of 5-fluorouracil, leucovorin and interferon-alpha 2b administered by 24 h infusion in metastatic colorectal carcinoma. <i>Anticancer Drugs</i> 1996 Jul;7(5):520-4.
	C6	Cella M et al. Plasmacytoid monocytes migrate to inflamed lymph nodes and produce large amounts of type I interferon. <i>Nat Med</i> 1999 Aug;5(8):919-23.
	C7	Chace JH et al. Bacterial DNA-induced NK cell IFN-gamma production is dependent on macrophage secretion of IL-12. <i>Clin Immunol Immunopathol</i> 1997 Aug;84(2):185-93.
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	C10	Froehler BC et al. Synthesis of DNA via deoxynucleoside H-phosphonate intermediates. <i>Nucleic Acids Res</i> 1986 Jul 11;14(13):5399-407.
	C11	Gaffney et al. Large-scale oligonucleotide synthesis by the H-phosphonate method. <i>Tetrahedron Lett</i> 1988;29(22):2619-22.
	C12	Galy A et al. Distinct signals control the hematopoiesis of lymphoid-related dendritic cells. <i>Blood</i> 2000 Jan 1;95(1):128-37.
	C13	Garegg et al. Nucleoside H-phosphonates. III. Chemical synthesis of oligodeoxyribonucleotides by the hydrogenphosphonate approach. <i>Tetrahedron Lett</i> 1986;27(34):4051-4.
	C14	Garegg et al. Nucleoside H-phosphonates. IV. Automated solid phase synthesis of oligoribonucleotides by the hydrogenphosphonate approach. <i>Tetrahedron Lett</i> 1986;27(34):4055-8.
	C15	Gill PS et al. Interferon-alpha maintenance therapy after cytotoxic chemotherapy for treatment of acquired immunodeficiency syndrome-related Kaposi's sarcoma. <i>J Biol Response Mod</i> 1990 Oct;9(5):512-6.
	C16	Goeddel DV et al. The structure of eight distinct cloned human leukocyte interferon cDNAs. <i>Nature</i> 1981 Mar 5;290(5801):20-6.
	C17	Goodchild J. Conjugates of oligonucleotides and modified oligonucleotides: a review of their synthesis and properties. <i>Bioconjugate Chem</i> 1990 May/June;1(3):165-87.
	C18	Gray PW et al. Expression of human immune interferon cDNA in E. coli and monkey cells. <i>Nature</i> 1982 Feb 11;295(5849):503-8.
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APPLICANT Hartmann et al.

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DEC 18 2003 PATENT & TRADEMARK OFFICE C23 C24 C25 C26 C27 C28 C29 C30 C31 C32 C33 C34 C35 C36 C37 C38 C39 C40	Halpern MD et al. In vitro inhibition of murine IFN gamma production by phosphorothioate deoxyguanosine oligomers. <i>Immunopharmacology</i> 1995 Feb;29(1):47-52.
	Hartmann G et al. CpG DNA and LPS induce distinct patterns of activation in human monocytes. <i>Gene Ther</i> 1999 May;6(5):893-903.
C23	Hartmann G et al. CpG DNA: a potent signal for growth, activation, and maturation of human dendritic cells. <i>Proc Natl Acad Sci USA</i> 1999 Aug 3;96(16):9305-10.
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C25	Hartmann G et al. Mechanism and function of a newly identified CpG DNA motif in human primary B cells. <i>J Immunol</i> 2000 Jan 15;164(2):944-53.
C26	Hartmann G et al. Specific suppression of human tumor necrosis factor-alpha synthesis by antisense oligodeoxynucleotides. <i>Antisense Nucleic Acid Drug Dev</i> 1996 Winter;6(4):291-9.
C27	Hartmann G et al. Spontaneous and cationic lipid-mediated uptake of antisense oligonucleotides in human monocytes and lymphocytes. <i>J Pharmacol Exp Ther</i> 1998 May;285(2):920-8.
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C29	Kimura Y et al. Binding of oligoguanosine to scavenger receptors is required for oligonucleotides to augment NK cell activity and induce IFN. <i>J Biochem (Tokyo)</i> 1994 Nov;116(5):991-4.
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C38	O'Doherty U et al. Dendritic cells freshly isolated from human blood express CD4 and mature into typical immunostimulatory dendritic cells after culture in monocyte-conditioned medium. <i>J Exp Med</i> 1993 Sep 1;178(3):1067-76.
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

APPLICANT Hartmann et al.

FILING DATE September 27, 2000

GROUP 1646

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51	641	Pulendran B et al. Distinct dendritic cell subsets differentially regulate the class of immune response in vivo. <i>Proc Natl Acad Sci USA</i> 1999 Feb 2;96(3):1036-41.
DEC 1 8 2003	C42	Qiu B and Chen M. Treatment of cutaneous T cell lymphoma with low doses of interferon alpha-2b. <i>Chin Med J (Engl)</i> 1996 May;109(5):404-6.
PATENT & TRADEMARK OFFICE	43	Ramanathan M et al. Inhibition of interferon-gamma-induced major histocompatibility complex class I expression by certain oligodeoxynucleotides. <i>Transplantation</i> 1994 Feb 27;57(4):612-5.
	C44	Rissoan M-C et al. Reciprocal control of T helper cell and dendritic cell differentiation. <i>Science</i> 1999 Feb 19;283(5405):1183-6.
	C45	Sato Y et al. Immunostimulatory DNA sequences necessary for effective intradermal gene immunization. <i>Science</i> 1996 Jul 19; 273(5273):352-4.
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	C49	Sun S et al. Type I interferon-mediated stimulation of T cells by CpG DNA. <i>J Exp Med</i> 1998 Dec 21;188(12):2335-42.
	C50	Tanaka Y et al. Natural and synthetic non-peptide antigens recognized by human gamma delta T cells. <i>Nature</i> 1995 May 11;375(6527):155-8.
	C51	Thomas R and Lipsky PE. Human peripheral blood dendritic cell subsets. Isolation and characterization of precursor and mature antigen-presenting cells. <i>J Immunol</i> 1994 Nov 1;153(9):4016-28.
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	C53	Tokunaga T et al. A synthetic single-stranded DNA, poly(dG,dC), induces interferon-alpha/beta and -gamma, augments natural killer activity, and suppresses tumor growth. <i>Jpn J Cancer Res</i> 1988 Jun;79(6):682-6.
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	C56	Uhlmann E and Peyman A. Antisense oligonucleotides: a new therapeutic principle. <i>Chem Rev</i> 1990 Jun;90(4):544-84.
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	C58	Wagner RW et al. Potent and selective inhibition of gene expression by an antisense heptanucleotide. <i>Nat Biotechnol</i> 1996 Jul;14(7):840-4.
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	C60	Yamamoto S et al. DNA from bacteria, but not from vertebrates, induces interferons, activates natural killer cells and inhibits tumor growth. <i>Microbiol Immunol</i> 1992;36(9):983-97.

FORM PTO-1449(Modifi d)

ATTY. DOCKET NO. C1039/7044

SERIAL NO. 09/672,126

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APPLICANT Hartmann et al.

FILING DATE September 27, 2000

GROUP 1646

DEC 18 2003 U.S. PATENT & TRADEMARK OFFICE	C63	Yamamoto S et al. In vitro augmentation of natural killer cell activity and production of interferon-alpha/beta and -gamma with deoxyribonucleic acid fraction from <i>Mycobacterium bovis</i> BCG. <i>Jpn J Cancer Res</i> 1988 Jul;79(7):866-73.
		Yamamoto S et al. Unique palindromic sequences in synthetic oligonucleotides are required to induce IFN and augment IFN-mediated natural killer activity. <i>J Immunol</i> 1992 Jun 15;148(12):4072-6.
	C63	Yamamoto T et al. Ability of oligonucleotides with certain palindromes to induce interferon production and augment natural killer cell activity is associated with their base length. <i>Antisense Res Dev</i> 1994 Summer;4(2):119-22.
	C64	Yi AK et al. Rapid immune activation by CpG motifs in bacterial DNA. Systemic induction of IL-6 transcription through an antioxidant-sensitive pathway. <i>J Immunol</i> 1996 Dec 15;157(12):5394-402.
	C65	Zhong RK et al. Human blood dendritic cell-like B cells isolated by the 5G9 monoclonal antibody reactive with a novel 220-kDa antigen. <i>J Immunol</i> 1999 Aug 1;163(3):1354-62.

\* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

EXAMINER

DATE CONSIDERED

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